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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **2,4-D choline:** Response to white papers submitted by Corteva relevant to runoff exposure and risks of 2,4-D to listed species in wetland and terrestrial habitats that receive runoff from Enlist-treated corn, cotton or soybean

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The Environmental Fate and Effects Division (EFED) is currently assessing the risks of 2,4-D choline (referred to here as "2,4-D") from applications of Enlist One and Enlist Duo on corn, cotton and soybean in 34 states to evaluate the renewal of the registration of these products. The current conclusions of this draft assessment indicate risk concerns for plant species that are federally listed as threatened or endangered plants (listed species) and located in terrestrial and wetland habitats, as well as listed species that rely upon plants for habitat and diet. Corteva, the registrant of the Enlist products, submitted a white paper (MRID 51667002) discussing their estimated exposures and risk quotients (RQs) for wetland and terrestrial plants. Corteva also submitted two white papers (MRIDs 51667001 and 51667102) that summarize available literature focusing on the effect of vegetative buffers on concentrations of 2,4-D in runoff. This document summarizes EFED's current risk conclusions for plants located in wetland and terrestrial habitats, including listed plant species. This document also summarizes EFEDs responses to some of the main points raised by Corteva in their three white papers. Additional details will be provided in EFED's final risk assessment for Enlist products.

Some of the main points raised by Corteva relate to EFED's 2016 risk assessment. Since 2016, EPA's methodology and approach to assessing run-off of herbicides has advanced. In the current assessment, EFED incorporated several improvements and refinements to the runoff risk evaluation (*e.g.,* includes 30-years of weather and EEC estimation; multiple and single applications at different crop stages; no applications when rain occurs within 24 hours of application; updated terrestrial and wetland plant conceptual models for exposure). EFED also corrected its previous calculation of runoff mass (the original edge of field EECs were incorrectly divided by 30 years instead of accounting for the years that were eliminated due to proximity of the application to a rainfall event). The current draft assessment identifies risk concerns for non-target plants in terrestrial and wetland environments from runoff exposure to 2,4-D.

In MRIDs 51667001 and 51667002, Corteva discussed analyses involving dicamba. EFED's risk assessment is focused on risks associated with Enlist, which includes exposures of non-target organisms to 2,4-D. EFED did not consider Corteva's analyses or discussions related to dicamba. It should be noted that the Enlist Duo product also includes glyphosate. Risks associated with glyphosate are also considered in EFED's risk assessment of the Enlist products. In this assessment, risks of glyphosate and 2,4-D were assessed separately for non-target organisms, but the listed species effects determination considered risks to listed species from both active ingredients. EFED notes that exposures of non-target plants to glyphosate also pose a risk to non-target plants in terrestrial and wetland habitats. Since glyphosate was not discussed in Corteva's white papers, it is not discussed further here. The discussion below relates to exposure and risks from 2,4-D due to Enlist product applications to corn, cotton and soybean.

In EFED's current draft assessment, drift is not a risk concern for plants located off of the treated fields due to spray drift mitigations already implemented on the Enlist labels. The primary transport route of concern for non-target plants is runoff. EFED estimated runoff exposure to terrestrial and wetland plants using the Plant Assessment Tool (PAT; available online at: https://www3.epa.gov/pesticides/nas/models-tools/pat-v2.zip). For terrestrial plants, runoff and erosion are modeled using PRZM. The model uses a mixing cell approach to represent water within the active root zone area of soil, and accounts for flow through the terrestrial plant exposure zone (T-PEZ) caused by both treated field runoff and direct precipitation onto the T-PEZ. Pesticide losses from the T-PEZ occur from transport (*i.e*., washout and infiltration below the active root zone) and degradation. Wetlands (wetland plant exposure zone, W-PEZ) are modeled using PRZM/Variable Volume Water Model (VVWM) and are then processed in PAT to estimate aquatic (mass per volume of water) and terrestrial (mass per area) concentrations. PAT has evolved from the runoff modeling approach used in the previous Enlist assessment (from 2014) and was used in the draft national-level biological evaluations for triazines and glyphosate. Corteva expressed concerns about the model's use of a 10:1 ratio of watershed area to wetland area; however, this ratio is a well-established conceptual approach in EFED's models (including TerrPlant and the Pesticide in Water Calculator). For this assessment, EFED is not revisiting the conceptual model of PAT, which includes the 10:1 ratio of the watershed area to wetland area for the W-PEZ.

Two literature studies that were identified by Corteva in MRID 51667001 (White *et al*., 1976 and Kenimer *et al*., 1987) provide practical information in calculating runoff flux from crop lands for comparison with model-generated runoff mass. The maximum runoff concentrations from these studies were used in estimating runoff flux of 2,4-D. The estimated runoff flux rates for the White *et al.* and Kenimer *et al.* studies were 0.015 pounds of acid equivalent per acre (lb ae/A) and 0.005 lb ae/A, respectively. EFED-calculated runoff fluxes from one application to the PAcorn and MScorn PWC

scenarios were 0.001 and 0.003 lb ae/A, respectively. The model-estimated fluxes are similar to that of the Kenimer *et al.* study; however, they are as much as an order of magnitude lower than that of the White *et al.* study. This difference between the White *et al*. study and PWC could be related to a larger runoff event simulated by White (1-in-50 year) than would be captured by the PWC estimates (average over a 30-year period). The standard PWC scenarios, including PAcorn and MScorn, were used to estimate runoff exposures to plants in terrestrial and wetland habitats for comparison to the flux estimates from the literature studies (White *et al*., 1976 and Kenimer *et al*., 1987). In MRID 51667001, Corteva calculated flux rates that were consistent with those calculated by EFED. Corteva took these flux rates a step further and compared them to plant toxicity endpoints to conclude that risk is low for plants. EFED does not agree with this comparison because it does not consider the characteristics of the receiving habitat (*e.g.*, watershed to water body ratio, volume of water within wetland). Therefore, comparing the flux rate to the toxicity endpoints is expected to underestimate exposure and also underestimate risk.

RQs in the current assessment were calculated using estimated environmental concentrations (EECs) from PAT and toxicity endpoints. For listed dicots and monocots, toxicity endpoints were No Observed Adverse Effects Concentration (NOAEC) values of 0.0075 lb ae/A and 0.030 lb ae/A, respectively (from a vegetative vigor study with Enlist duo; MRID 49903202). Based on the current labels for Enlist, 2,4-D listed plant RQs for wetlands range 13-36 for dicots and 3.3-8.9 for monocots. For listed plants in terrestrial habitats, the RQ range is 4.8-10 for dicots and 1.2-2.5 for monocots. Since all of these RQs exceed the listed plant Level of Concern (LOC) of 1, there are potential risks to listed plants that inhabit terrestrial and wetland habitats that receive runoff from corn, cotton and soybean fields. If RQs remain above the LOC, EFED will make May Affect (MA) determinations for several listed plants. In MRID 51667002, Corteva reported RQs calculated using PAT and vegetative vigor endpoints that also exceed the LOC. Based on the RQs calculated by EFED (which differ than those calculated by Corteva), mitigations resulting in 97% reduction in runoff would be needed to result in No Effect (NE) determinations for all listed species. If reductions less than 97% could be achieved, NE determinations could be made for some, but not all species. For instance, a reduction of 60% would mitigate risks to terrestrial monocots and a reduction of 89% would mitigate risks for terrestrial dicots and wetland monocots. It should be noted here that risks are also identified for listed animals based on impacts to non-listed plants. Mitigating risks to listed plants would also address risk concerns for indirect effects on listed animals.

Corteva stated in MRID 51667001:

> "Corteva's review indicated that runoff concentrations of 2,4-D will be low and unlikely to cause off-field impacts. It is also important to note that in the current labeling of Enlist Duo and Enlist One herbicides, applications are prohibited when rain is expected within 24 hours, so any field studies with rainfall events within 1 day can further be considered extreme cases. Based upon the weight of evidence, the potential for any impact to off-target plant species from runoff following applications of Enlist herbicides is extremely low and therefore a reasonable no effect determination can be made for off-field plants."

EFED disagrees with this conclusion. EFED considered rainfast restrictions in the modeling estimates. As indicated above, EFED's risk quotients that consider rainfast restrictions for listed and non-listed plants in terrestrial and aquatic plants are above the LOC of 1. Therefore, there are risk concerns identified for an individual listed plant or an animal that depends upon plants for habitat or diet. The currently available data and analyses do not support a No Effect determination for listed species that are expected to inhabit terrestrial and wetland habitats that receive runoff from corn, cotton or soybean

fields treated with Enlist. In order to achieve a No Effect determination for all listed species, additional mitigations would be needed.

Corteva indicated that 5-m vegetative buffers would be sufficient to mitigate runoff risks associated with 2,4-D such that No Effect determinations could be made for listed species (MRID 51667102). In that white paper, Corteva discussed two studies from the literature that evaluated the effectiveness of grassed buffers in removing 2,4-D from runoff (Cole *et al*. 1997 and Asmussen *et al*. 1977). EPA agrees that a well-maintained vegetative buffer could potentially intercept some amount of 2,4-D laden runoff (both soluble and sediment-bound) prior to reaching non-target areas. EFED evaluated Cole *et al*. 1997 and Asmussen *et al*. 1977. Cole *et al*. observed variable results in two different study periods when evaluating effectiveness of turf (bermudagrass) buffers (as long as 5 m). When antecedent soil moisture and runoff volume was lower, 2,4-D concentration reductions ranged 76-96%. At the same site, reductions in 2,4-D concentrations ranged 8-55% when antecedent soil moisture and runoff volume were higher. This suggests that turf buffers of 5 m or less are not effective at reliably reducing 2,4-D concentrations in runoff. Asmussen *et al*. (1977) observed approximately 70% retention of 2,4-D mass within a much longer 24-m grassed waterway. In this study, antecedent soil moisture conditions did not influence the amount of 2,4-D that was removed. Although the 70% reduction observed by Asmussen *et al.* is not substantial enough to achieve the amount of reduction needed to come to a No Effect determination for all listed species, that level of reduction could reduce exposure and associated risk for non-listed and listed plants. This study represents one study that was conducted at a single location and with a unique buffer and set of field conditions. Additional studies would be needed to understand the variability in removal rates across different field and soil conditions as well as different types of vegetative buffers. Given the variability in effectiveness of vegetative buffers in the two literature studies and that most of the reduction of 2,4-D observed was well below what is needed to achieve a No Effect determination, a 5-m vegetative buffer as the only risk mitigation for Enlist products is insufficient to achieve No Effect determinations.

Vegetative buffers are designed to intercept runoff and minimize soil erosion. Buffers can reduce the amount of sediment and pollutants carried by runoff to adjacent surface water bodies. As described above, the two available 2,4-D specific studies demonstrated a high degree of variability in the effectiveness of the filter strips tested under the conditions of those studies. Reichenberger *et al.* (2007) reviewed 180 publications and evaluated many aspects related to the effectiveness of vegetative buffers in reducing pesticide loads into adjacent water bodies. They concluded that the effectiveness of vegetative buffers to reduce pesticide loading into an adjacent surface water body depended on many factors, such as topography, field conditions, soil types, antecedent moisture conditions, rainfall intensity, properties of the pesticide, application methods, width of the vegetative buffer and types of vegetation within the buffer strip. Vegetative buffer maintenance was determined to be critical for their continuing effectiveness in intercepting runoff loads and mitigating pesticide loadings from runoff into water bodies. Long-term effectiveness of vegetative buffers required regular maintenance including excavation to remove overburdens of sediments, repairing vegetation damage, and removing over-mature vegetation or invasive noxious weeds (USDA, 2000). Additional changes to the Enlist labels (*e.g.*, increasing the rainfast time period, reducing the number of applications) combined with buffers like those used by Asmussen *et al.* could be helpful to mitigate risks to listed species. In order to maintain the effectiveness of buffers, they would need to be well-maintained.

In MRID 51667102, Corteva noted that as part of EPA's 2016 assessment, EPA included some additional characterization regarding mitigations that reduce potential risk to plants associated with run-off. More specifically, Corteva noted that in that assessment, EPA stated that mitigations such as restricting the

application of Enlist to prevent its use within 24 hours of a rainfall event would prevent plants from being adversely affected. They further noted that EPA concluded "As 2,4-D is primarily a foliarly-absorbed herbicide with limited root uptake, the EPA expects that much of the off-site plant community will not experience foliar contact with the herbicide in runoff sheet flow. A 24-hour rainfast period is also included on the label to reduce mass runoff; therefore, the EPA concludes that all available lines of evidence support the conclusion that runoff exposure should not occur for off-field listed and non-listed plants." Corteva then stated that it "maintains that the compounded conservatisms acknowledged in the 2016 assessment remain applicable to Enlist One and Enlist Duo applications today" and that the same logic applied in the 2016 decision can still be used to address potential risk to plants from run-off. EPA does not agree that the current information supports Corteva's assertion because the current evidence no longer support's EPA's 2016 conclusion.

As discussed earlier, when considering the currently available lines of evidence, EFED's current draft risk assessment for the Enlist products identifies risks to non-target listed and non-listed species of plants exposed to 2,4-D in runoff. This includes plants inhabiting terrestrial and wetland habitats. This is based on consideration of multiple PWC scenarios and a range of sensitivities in available test species and endpoints. EFED's current risk conclusions are supported by the following multiple lines of evidence related to both the exposure estimation and effects characterization. First, EPA estimated exposure using multiple standard PWC scenarios available for corn, cotton and soybean. As described above, runoff flux estimates from the PWC field are consistent with flux rates from empirical studies (White *et al*., 1976 and Kenimer *et al*., 1987). This provides EPA with greater confidence in its model based EECs. Second, PAT, which is EFED's current, more advanced model for estimating exposure to plants in terrestrial and wetland habitats, considers multiple factors that can influence exposure to plants, including: soil properties, rainfall events (including 30 years of weather data), multiple applications, environmental fate and transport of 2,4-D and receiving habitat characteristics. As such, EPA can now evaluate (and has evaluated) the potential impact of mitigations such as a 24 hour rainfast requirement on resulting EECs. For terrestrial and wetland habitats, EECs for all modeled PWC scenarios exceed the vegetative vigor EC_{25} and NOAEC values with and without a 24 hour rainfast requirement. This indicates that exposure is sufficient to result in RQs that exceed the LOC for both non-listed and listed species of dicots and monocots. In addition, for terrestrial habitats, EECs also exceed the seedling emergence EC_{25} and NOAEC for dicots for many PWC scenarios (monocot seedling emergence endpoints are not exceeded by terrestrial EECs). For wetland habitats, EECs exceed the seedling emergence EC_{25} and NOAEC for dicots for all PWC scenarios (the monocot seedling emergence NOAEC is only exceeded by a wetland EEC for one PWC scenario). Therefore, plants may be at risk from root uptake or foliar contact with 2,4-D in runoff. When considering all of the available vegetative vigor data for multiple test species, the upper-bound wetland and terrestrial EECs exceed the EC_{25} values for all species For wetlands, EECs are an order of magnitude above the available toxicity endpoints. Last, in the previous assessment for Enlist, EFED's refined model runs with PRZM did not account for the ratio of the watershed area to a wetland area, resulting in higher EECs in the current assessment. In addition, EFED's previous assessment only considered exposure to the seedling emergence phase. The current assessment also considers exposure to non-target plants through vegetation (*i.e*., contact of runoff with leaves and stems). When considering exposure of plants to runoff in terrestrial or wetland environments, it would be inappropriate to assume no contact with leaves because there are many growth forms of monocot and dicot plants that have leaves on the soil surface, submerged in water, or otherwise in position that would result in contact with runoff. Since the vegetative vigor endpoints are more sensitive than seedling emergence, this also resulted in higher RQs. As such, runoff buffers or other possible mitigating factors considered in the 2016 assessment are insufficient to achieve a No Effect determination for plants.

In summary, EFED reviewed the three 2,4-D runoff-related white papers that were submitted by Corteva. The empirical studies evaluating runoff of 2,4-D generally support the runoff flux estimated using EFED's standard runoff model. When considering the current risk picture, EFED does not agree with Corteva that the available data support a conclusion that risks to non-target plants can be considered low or that no effect determinations can be made for listed plants exposed to 2,4-D through runoff. EFED's current risk conclusions are based on multiple lines of evidence indicating a concern for growth effects to plants in terrestrial and wetland areas. Since the previous assessment for Enlist, EFED has updated its approach for estimating exposure and risk to plants, which accounts for exposure and effects not previously considered for Enlist. EFED does not agree that a 5-m vegetative buffer is sufficient (as the sole mitigation) to achieve No Effect determinations for all listed species. In order to make No Effect determinations for listed species, as much as 97% reduction in exposure through runoff would be needed. Available studies evaluating the effectiveness of vegetative buffers in reducing 2,4-D runoff exposure vary in results; however, most indicate a less than 97% reduction in 2,4-D concentrations in runoff. Specifically designed and well-maintained vegetative buffers could help to reduce exposure through runoff; however, additional mitigations would be needed to achieve No Effect determinations for all listed species.

References

MRID 51667001. Schlier III, J. and Havens, P. Position Paper. 2021. 2,4-D Runoff Field Studies. Corteva Agriscience Crop Protection Regulatory Sciences.

MRID 51667002. Havens, P. 2021. Comparative evaluation of Dicamba and 2,4-D runoff risk to non-target plants from application to HT crops – updated version. Corteva Agriscience Crop Protection Regulatory Sciences.

MRID 51667102. Schlier III, J. and Fleming, 2021. Position Paper: Review of Runoff Mitigation Technology. Corteva Agriscience Crop Protection Regulatory Sciences.Asmussen, L.E., A.W. White Jr., E.W. Hauser, and J.M. Sheridan. 1977. Reduction of 2,4-D load in surface runoff down a grassed waterway. J. Environ. Qual.6(2):159-162.

Asmussen, L.E., A.W. White Jr., E.W. Hauser, and J.M. Sheridan. 1977. Reduction of 2,4-D load in surface runoff down a grassed waterway. J. Environ. Qual.6(2):159-162.

Cole, J.T., J.H. Baird, N.T. Basta, R.L. Huhnke, D.E. Storm, G.V. Johnson, M.E. Payton, M.D. Smolen, D.L. Martin, and J.C. Cole. 1997. Influence of buffers on pesticide and nutrient runoff from bermudagrass turf. J. Environ. Qual. 26:1589-1598.

Kenimer, A.L., Mostaghimi, S., Young, R.W. Dillaha, T.A., and Shanholtz. 1987. Effects of Residue Cover on Pesticide Loess from Conventional and No-tillage Systems. Transactions of the ASAE 30: 953-959.

Reichenberger, S. M. Bach, A. Skitschak, and H. Frede, 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness: A Review. Science of the Total Environment 384:1-35.

USDA-NRCS, 2000. Conservation Buffers to Reduce Pesticide Losses. U.S. Department of Agriculture–Natural Resource Conservation Service. https://www.nrcs.usda.gov/Internet/FSE_DOCUMENTS/nrcs144p2_030970.pdf

USEPA. 2016. 2,4-D Choline Salt: EFED Ecological Risk Assessment and Listed Species effects determinations for GF2726 formulation of 2,4-D choline on GE corn, GE cotton, and GE soybean in AL, AR, AZ, CO, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, NJ, NM, NY, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV. Environmental Fate and Effects Division, Office of Pesticide Programs, Washington, D.C. (DP 428301).

USEPA. 2014. Addendum to 2,4-D Choline Salt Section 3 Risk Assessment: Refined Terrestrial Plant Exposure Estimates and Effects Determination. Environmental Fate and Effects Division, Office of Pesticide Programs, Washington, D.C. (DP 423309).

White, A.W., A.D. Barnett, B.G. Wright, and J.H Holliday. 1976. Atrazine losses from fellow land caused by runoff and erosion. Environ. Sci. Technol. 1: 740-744.